

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Investigating the effect of active cycle breathing technique on pain, anxiety and blood oxygen saturation of patients undergoing coronary artery bypass graft (CABG)

Protocol summary

Study aim

Determining the effect of active breathing cycle technique on pain, anxiety and saturation Arterial blood oxygen in patients undergoing coronary bypass surgery

Design

Parallel group randomized trial in which participants will be divided into two groups by permuted block randomization. Sample size was calculated 76.

Settings and conduct

After referring to the CCU and heart departments of Al-Zahra Heart Hospital in Shiraz, the researcher selects people according to the entry and exit criteria and includes them in the study if they give informed consent. In the intervention group, in addition to receiving routine care, breathing exercises are taught to the patients one day before the surgery by the researcher or the researcher's assistant, and after surgery and extubation, breathing exercises are taught on two consecutive days in two shifts, morning and evening. It is done with the guidance of the researcher. Patients in the control group will receive routine care, including the use of an incentive spirometer. In the intervention group, anxiety, pain and arterial blood oxygen saturation will be assessed once before the intervention and then after each time the active breathing cycle technique is performed. In the control group, the variables will be measured in the same time intervals.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age who need coronary artery bypass surgery as determined by the doctor and have no history of open heart surgery

Intervention groups

In both groups, on the second day after the operation and extubation, all the variables will be measured, then in the intervention group active breathing cycle technique and in the control group, routine interventions will be performed. In both groups, all the variables will be

measured. after interventions.

Main outcome variables

pain, anxiety, and blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044347N6**

Registration date: **2023-10-18, 1402/07/26**

Registration timing: **prospective**

Last update: **2023-10-18, 1402/07/26**

Update count: **0**

Registration date

2023-10-18, 1402/07/26

Registrant information

Name

Fatemeh Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of active cycle breathing technique on pain, anxiety and blood oxygen saturation of patients undergoing coronary artery bypass graft (CABG)

Public title

the effect of active cycle breathing technique on pain, anxiety and blood oxygen saturation of patients undergoing coronary artery bypass graft (CABG)

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age above 18 years Candidate for coronary artery bypass surgery according to physician's diagnosis Not having a known history of severe respiratory and lung disease Ability to perform breathing exercises and use the active cycle of breathing No previous history of open heart surgery Not having a history of known mental illness or under treatment with anti-anxiety and sedative drugs before surgery

Exclusion criteria:

Unwillingness to stay in the study Occurrence of critical complications after surgery including shock, critical hypertension crisis, cardiac tamponade The occurrence of dangerous dysrhythmias such as atrial fibrillation and ventricular tachycardia Mechanical ventilation for more than 48 hours after surgery The need for reoperation during the hospitalization period

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting eligible individuals to participate in the study based on inclusion criteria, these individuals will be assigned to two study groups based on double randomized permutation block with foursome blocks. The random list is generated by a statistician using "Random Allocation" software. Foursome blocks are the combination of different status such as: ABBA, BAAB, BABA, ABAB, BBAA, AABB. Using random list that is generated by computer, 19 blocks will be selected to form the two study groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Schools of Nursing and Midwifery, Management and Medical Information S

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Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

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7134814336

Approval date

2023-06-17, 1402/03/27

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1402.073

Health conditions studied**1****Description of health condition studied**

patients undergoing coronary artery bypass graft (CABG)

ICD-10 code

T82.8

ICD-10 code description

Other specified complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes**1****Description**

pain

Timepoint

From the second day after surgery and extubation, once before starting the intervention and then after performing each phase of the active breathing cycle technique

Method of measurement

visual analogue of scale pain

2**Description**

anxiety

Timepoint

From the second day after surgery and extubation, once before starting the intervention and then after performing each phase of the active breathing cycle technique

Method of measurement

Spielberger questionnaire

3

Description

Oxygen saturation of arterial blood

Timepoint

From the second day after surgery and extubation, once before starting the intervention and then after performing each phase of the active breathing cycle technique

Method of measurement

Pulse oximetry device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, breathing exercises are taught to the patients one day before the surgery by the researcher or the researcher's assistant. From the second day after the surgery and extubation, in the morning and evening shifts, the patients are encouraged to use incentive spirometry as a routine care. They also practice and implement the active cycle of breathing technique. This technique is performed in three stages; The first step is breathing control. At this stage, breathing is done slowly through the nose. If it is not possible for the patient to breathe through the nose, it is done through the mouth with pursed lips. During this stage, the patient is encouraged to keep his peace by closing his eyes and keeping himself away from any tension. The second step is to practice expanding the chest wall to provide airflow in the small airways. At this stage, air flows deeply, slowly and continuously through the nose into the lungs, so that the chest wall expands. The air is held for 2 to 3 seconds and then slowly exhaled through the mouth. This step is repeated 3 times. The final stage is the coughing stage and an integral part of this technique. In this stage, coughing is done through the mouth and throat. For this purpose, the patient takes a deep breath with the mouth open and with the help of respiratory muscles and then coughs. Active breathing cycle technique will be performed from the day after extubation of each patient in two days and in two shifts, morning and evening. Each time will be 3 sessions and each session will last for 10 minutes with a 15 minute break between them. In addition to the active breathing cycle technique, the patients in the intervention group will receive routine care including the use of an incentive spirometer. The level of anxiety, pain and arterial blood oxygen saturation will be assessed by the researcher or

research assistant once before the intervention and then after each time the active breathing cycle technique is performed.

Category

Treatment - Other

2

Description

Control group: In the control group, patients receive the usual care, which includes the use of an incentive spirometer, according to the hospital routine. Breathing with a spirometer takes 10 to 20 deep breaths in each shift; This breathing is done in such a way that after the end of inhalation, the patient holds his breath for three seconds and by removing the device, exhales slowly through the mouth. This breathing exercise is performed in every shift until the patient is discharged. It is done sitting or semi-sitting, and after performing this technique, the level of anxiety, pain, and oxygen saturation of the arterial blood of the patients is measured from the day after the extubation of each patient in two days and in two shifts, morning and evening, by the researcher or the researcher's assistant

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Heart Charity Hospital

Full name of responsible person

Dr Hojjatollah Roosta

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Astaneh Three Ways, Sibouyeh Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Shirazi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable